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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,555	09/22/2000	Ypke Vincentius Johannes Maria van Oosterhout	4541US	2631

24247 7590 10/18/2002

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	12

DATE MAILED: 10/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/668,555	Van Oosterhout et al.
Examiner	**Art Unit**
Ron Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-8, 10-13, 15, and 18-26* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-8, 10-13, 15, and 18-26* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Claims 1-8,10-13,15,18-26 are under consideration. Claims 1-4,7,8,10-13,15,18,19 have been amended. Claims 24-26 have been added.

RESPONSE TO APPLICANTS ARGUMENTS

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-8,10-13,15,18-26 are rejected under 35 U.S.C. 102(a) as being anticipated by van Oosterhout et al. for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Regarding the Oosterhout and Emst declarations filed 6/11/2002, the MPEP section 715.05, page 700-208 states that a declaration must include an acknowledgment by the declarant that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon. The declarant must set forth in the body of the declaration that all statements made of the declarant's own knowledge are true and that all statements made on information and belief are believed to be true.

4. Claims 1-5,7-13,15,18,19,21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Scannon et al. (WO 89/06967) for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Scannon et al. teach use of a pharmaceutical composition containing antiCD3

antibody/ ricin A and antiCD7 antibody/ ricin A to treat GVHD (see page 4, first paragraph, page 6, first paragraph, page 12, page 13). Scannon et al. teach that the immunotoxin can be prepared by chemical linkage (see page 14 and 15). Scannon et al. teach that the composition can contain antibody immunotoxins against the T cell markers CD3, CD7, CD5 (page 4, first paragraph). The pharmaceutical composition taught by Scannon et al. (see page 10, last paragraph) has the dosage recited in claims 11 and 12, because said recited dosage is based on the subject's size and the subject could be of any size. As per the definition of "derivative" on page 5 of the specification, a derivative of an IgG2B antibody would be any antibody of any isotype which binds CD3 or CD7.

Regarding applicants comments about unexpected results, unexpected results are irrelevant to a rejection under 35 U.S.C. 102. Regarding applicants comments about "consisting essentially of", the current PTO policy is to treat said language as equivalent in scope to comprising. Furthermore, if it is applicants intent to limit the composition to containing only antiCD3 and antiCD7 antibodies then this issue could be unambiguously addressed by a claim that recited that the composition did not contain antibodies other than those that bind CD3 and CD7.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-8,10-13,15,18-26 stand rejected under 35 U.S.C. 103(a) as being

unpatentable over Scannon et al. (WO 89/06967) in view of Thorpe et al. (US 6,261,535) for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Scannon et al. teach use of a pharmaceutical composition containing antiCD3 antibody/ ricin A and antiCD7 antibody/ ricin A to treat GVHD (see page 4, first paragraph, page 6, first paragraph, page 12, page 13). Scannon et al. teach that the immunotoxin can be prepared by chemical linkage (see page 14 and 15). Scannon et al. teach that the composition can contain antibody immunotoxins against the T cell markers CD3, CD7, CD5 (page 4, first paragraph). The pharmaceutical composition taught by Scannon et al. (see page 10, last paragraph) has the dosage recited in claims 11 and 12, because said recited dosage is based on the subject's size and the subject could be of any size. As per the definition of "derivative" on page 5 of the specification, a derivative of an IgG2B antibody would be any antibody of any isotype which binds CD3 or CD7. Scannon et al. do not teach the claimed invention which uses deglycosylated ricin A. Thorpe et al. teach use of deglycosylated ricin A in immunotoxins (see column 2, second paragraph). Thorpe et al. teach that use of deglycosylated ricin A in immunotoxins results in decreased hepatotoxicity (see column 2, second paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Scannon et al. teach the claimed invention except for use of deglycosylated ricin A while Thorpe et al. teach use of deglycosylated ricin A and that use of deglycosylated ricin A in immunotoxins results in decreased hepatotoxicity (see column 2, second paragraph).

Regarding applicants comments about "consisting essentially of", the current PTO policy is to treat said language as equivalent in scope to comprising. Furthermore, if it is applicants intent to limit the composition to containing only antiCD3 and antiCD7 antibodies then this issue could be unambiguously addressed by a claim that recited that the composition did not contain antibodies other than those that bind CD3 and CD7. Regarding applicants comments about unexpected results, the only claims specifically rejected under 35 U.S.C. 103 that were not rejected under 35 U.S.C. 102 are drawn to use of deglycosylated ricin A in immunotoxins. There is no evidence of record that the use of deglycosylated ricin A results in the purported unexpected results referred to by applicant. Furthermore, the advantages of using deglycosylated ricin A in an immunotoxin were well

known in the art (Thorpe et al. teach use of deglycosylated ricin A and that use of deglycosylated ricin A in immunotoxins results in decreased hepatotoxicity).

7. No claims are allowed.

8. The substitute specification filed has not been entered because it does not conform to 37 CFR 1.125(b)because it lacks the required statement under 37 CFR 1.125(b)(1).

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number

is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644